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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,702	11/25/2003	Elfatih Elzein	01-157-CIP	7434

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CV THERAPEUTICS, INC.
3172 PORTER DRIVE
PALO ALTO, CA 94304

EXAMINER

KHARE, DEVESH

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,702

Applicant(s)

ELZEIN ET AL.

Examiner

Devesh Khare

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 and 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendments and remarks filed on 03/30/2006 are acknowledged. Claims 24-26 and 28-33 have been cancelled. Applicant's election to prosecute the invention of Group I (claims 1-23 and 27) without traverse is acknowledged.

The rejection under 35 U.S.C. 103(a) of the Office Action dated 11/21/2005 has been withdrawn in response to applicant's remarks.

Claims 1-23 and 27 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6,11,13,15,16, 20-22 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention of record.

In the absence of the specific moieties intended to effectuate modification by substitution or attachment to the chemical core claimed, the term "optionally substituted" in all occurrences renders the claims in which it appears indefinite wherein applicant fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicant regards as those which will facilitate substitution, requisite to identifying the compound of matter claimed.

Rejection Maintained

Rejection of claims 1-6,11,13,15,16, 20-22 and 27 under 35 U.S.C. 112, second paragraph, is maintained for the reasons of record.

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Response to Arguments

Applicant's arguments filed on 3/30/2006 traversing the rejection of claims 1-6, 11, 13, 15, 16, 20-22 and 27 under 35 U.S.C. 112, second paragraph have been fully considered but they are not persuasive. The specification does not define the "optionally substituted" moieties. The term "Optionally substituted" is not defined at page 13, line 1. Furthermore, pages 5 and 10 failed to define said term as applicant asserts. For example see pages 4-5 where alternative preferences for the term "alkyl" are presented. Additionally, it appears that the term embraces ethers, amines, and thioethers which would be outside the scope of what one of ordinary skill in the art would consider as being an "alkyl" group.

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-23 and 27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Zablocki et al. (claims 1-28 of U.S. Patent No. 6,214,807; claim 1 of U.S. Patent 6,855,818; and claims 1, 5 and 6 of U.S. Patent 6,770,634) in view of Klotz et al. (Naunyn-Schmiedeberg's Arch Pharm (1999), 360, 103-108) of record.

The instant invention is directed to a compound of the formula I (adenosine prodrug, claim 1) wherein C-2 is substituted pyrazolyl or substituted triple bond ($-C\equiv C-$). Additional limitations include and a pharmaceutical composition, in a pharmaceutically acceptable

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carrier, N-6 is substituted with an alkyl or aryl group, pyrazole group is substituted with a methoxyphenyl, a benzyl, a chlorobenzylaminocarbonyl or a pyrid-2-yl (specifically in claims 7-10,12,14,17 and 18) and triple bond ($-C\equiv C-$) is substituted with a phenyl and alkylene groups (specifically in claim 23).

Like the instantly claimed invention, the Zablocki et al's patents discloses the 2-adenosine C-pyrazole compounds and compositions wherein pyrazole is substituted with aryl and heteroaryl groups (see claim 1). The 2-adenosine C-pyrazole compounds are within the scope of the instant claims. The instantly claimed invention differs from the Zablocki et al's patents by claiming adenosine derivatives wherein C-2 is substituted with a substituted triple bond ($-C\equiv C-$). It is noted that Zablocki et al. do not disclose the N-substitution at C-6.

The Klotz et al. disclose 2-substituted N-ethylcarboxamidoadenosine derivatives (see abstract). Klotz et al. disclose a substituted triple bond ($-C\equiv C-$) substitution with alkyl chains and aryl groups at C-2 in adenosine (page 105, fig 1). Klotz et al also disclose the N-6- aryl substitution in adenosine derivatives (page 103, 2nd col., last para.).

Moreover, the structure of the instant elected compound of the formula I (adenosine prodrug, claim 1) wherein C-2 is substituted pyazolyl or substituted triple bond ($-C\equiv C-$) is substantially similar to the structures of Zablocki et al's 2-adenosine C-pyrazole compound. Also, the replacement of "H" with "CH₃" (lower alkyl) at the N-6 position amounts to an obvious homolog. Therefore, one of ordinary skill in the art would have

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reasonably expected that the instant elected compounds would have possess the similar activity as its homologs because of the substantially close structural relationship.

The examiner notes the instant claims and the Zablocki et al.'s patents claims do indeed substantially overlap therefore obviousness-type double patenting rejection is necessary to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. Therefore the claims are co-extensive.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's amendments traversing the rejection of claims 1-23 and 27 under obviousness-type double patenting rejection have been fully considered but they are not persuasive.

Applicant argues, "it is noted that Zablocki et al. do not disclose the N-substitution at C-6" and "instant claims are different from those in Zablocki et al".

It is noted that the structure of the instant elected compound of the formula I (adenosine prodrug, claim 1) wherein C-2 is substituted pyazolyl or substituted triple

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bond ($-C\equiv C-$) is substantially similar to the structures of Zablocki et al's 2-adenosine C-pyrazole compound. Also, the replacement of "H" with "CH₃" (lower alkyl) at the N-6 position amounts to an obvious homolog. Therefore, one of ordinary skill in the art would have reasonably expected that the instant elected compounds would have possess the similar activity as its homologs because of the substantially close structural relationship.

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at

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(571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
May 12, 2006



Anna Jiang, Ph.D.
Supervisory Patent Examiner
Technology Center 1600